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August 27, 2007

**BY E-FILING and HAND DELIVERY**

The Honorable Mary Pat Thyng  
United States Magistrate Judge  
United States District Court  
844 King Street  
Wilmington, DE 19801

Re: Roquette Frères v. SPI Pharma, Inc., et al.  
C.A. 06-540 (\*\*\*)

Dear Judge Thyng:

This responds to the letter filed by SPI Pharma, Inc. on August 24, 2007, which identified those categories for which SPI contends it is entitled to additional discovery from Roquette.

Roquette has already produced, after searching its records, all of the located information within every category identified in SPI's letter with one exception; Roquette objects to SPI's request for identification (and actual samples) of products that utilize inventions described in unrelated foreign patents.

We address each of SPI's five-listed categories in turn.

**1. Protocols and Raw Data**

Roquette has never objected to producing non-privileged information related to the tests it performed on SPI's accused products. Indeed, Roquette has produced and supplemented such information. SPI now requests only that this Court "confirm" Roquette's response that it has conducted a reasonable search and has produced all non-privileged

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responsive documents that were located.<sup>1</sup> SPI has no basis for questioning the integrity of Roquette's thrice confirmed response.

## **2. Products Described in Unrelated Foreign Patents**

As SPI's sole category for which a dispute actually exists, SPI asks the Court to require Roquette to provide a list – and actual samples – of products that utilize not the claims of the patent-in-suit but the "invention" of French Patents 2,571,045 and 2,571,046. The French patents are not related to any patent family that includes the patent-in-suit, were published more than seven years before even the priority filing date of the patent-in-suit, and other than being discussed in the specification of the patent-in-suit bear no relation to this case.

Even more removed from this case, SPI in its letter expands its request to include any products that utilize inventions of counterparts to those prior French patents.

To the extent that the French '045 and '046 patents are discussed in the specification of the patent-in-suit, those patents themselves might be relevant to this case. The prosecution histories of those prior French patents are not relevant. Nonetheless, in a spirit of cooperation Roquette produced them at SPI's request.

However, SPI's request for identification of products, if any actually exist, that utilize the inventions described in those prior, unrelated French patents is entirely beyond any possible relevance to Roquette's claims or SPI's defenses. SPI's request for actual samples of unrelated products is even more removed. The request is make-work, unreasonably burdensome, and would require speculation as to whether a product would or would not be responsive.

## **3. Conception and Reduction to Practice**

Roquette produced documents relating to conception and reduction to practice, despite its continued objection that conception and reduction to practice are not at issue in this case because SPI has not asserted with specificity any invalidity contention to which that information might be relevant. Roquette further identified those documents by specific Bates Numbers, which specified documents provide the requested narrative of events.

SPI contends that it needs to review original laboratory notebooks to confirm that Roquette has not withheld information (despite Roquette's repeated confirmation that it has not). After further review by French counsel, Roquette again confirms that the non-produced portions of the original laboratory notebooks contain only non-responsive information including information which is highly sensitive and confidential. (The notebooks include research on other

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<sup>1</sup> Roquette's letter of August 17, 2007, omitted from SPI's submitted exhibits but attached as Exhibit 1 hereto, stated for the third time that Roquette has no objection to producing non-privileged documents regarding the tests on the accused products, including protocols and raw data associated with those tests.

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projects unrelated to the patent-in-suit). Despite the protective order in place, Roquette should not be required to reveal business sensitive information that is unrelated to this action and non-responsive to SPI's information requests.

#### **4. Patent Prosecution Files**

SPI requested that Roquette provide the prosecution history for each and every foreign counterpart to the patent-in-suit. Despite its objection that foreign prosecution histories are not relevant to any issue in this case regarding the U.S. patent, and despite the fact that such prosecution histories are publicly available and thus readily obtained by SPI, Roquette agreed to provide the requested prosecution histories and has been producing them as they are obtained.<sup>2</sup>

SPI now seeks the attorney prosecution files for those foreign patents. Correspondence between foreign prosecuting attorneys and their clients in foreign applications not related to the patent-in-suit are simply not relevant to any issue in this case, and in any event would be privileged.

Documents located in the prosecution files for the patent-in-suit have been produced or listed on Roquette's privilege log.

#### **5. Secondary Indicia Evidence**

SPI contends that secondary indicia of nonobviousness is relevant to SPI's invalidity defenses and counterclaims. However, SPI's invalidity defenses and counterclaims consist solely of a bald reference of 35 U.S.C. §§ 101, 102, 103 and 112, along with an unexplained list of the patents cited in the patent-in-suit or certain counterparts thereof.

Roquette considers that secondary indicia of nonobviousness is not at issue unless and until SPI identifies with meaningful specificity the grounds upon which it bases its defense and counterclaim of obviousness.

Despite its objection, Roquette agreed to search for responsive documents and to produce those that are located and non-privileged. Roquette has produced those documents. Roquette will supplement its production of responsive documents to the extent the scope of SPI's request is revealed through SPI's specified invalidity contentions of obviousness if and when those contentions are presented.

As the foregoing underscores, SPI's letter presents the Court with only one category for which any real dispute exists. As to that category, Roquette considers its objection

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<sup>2</sup> As SPI acknowledges in its letter at footnote 1, the requested prosecution histories have already numbered nearly 600 pages, imposing significant and needless expense on Roquette.

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to be well-taken. Accordingly, Roquette requests that each of SPI's listed discovery requests be denied.

Respectfully,



Benjamin J. Schladweiler (#4601)

cc: Dr. Peter Dalleo, Clerk (By e-filing)  
John W. Shaw (By e-mail)  
Oren D. Langer (By e-mail)

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## **EXHIBIT 1**

# YOUNG & THOMPSON

International Patent & Trademark Law

*Established 1903*

Emil Bönnelycke  
1875–1936

William H. Young  
1902–1958

Irvin S. Thompson  
1903–1979



August 17, 2007

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Morgan, Lewis & Bockius LLP  
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New York, NY 10178-0060

**Via Electronic Mail and Federal Express**

Re: *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540 (\*\*\*)  
Our Ref. 0600-269

Dear Oren,

This responds to your letters of July 30 and August 15, 2007, regarding SPI's discovery concerns.

**I. Roquette's Testing of Accused Mannogem™ EZ Product**

As we previously twice informed you, first during the July 9, 2007 teleconference and again in our July 20, 2007 letter, Roquette has no objection to providing non-privileged information related to Roquette's testing of accused products, including test methodologies, protocols and raw data. Roquette produced that information in its first document production in May, including the '777 patent which describes the relevant test methodologies and protocols, and in its supplemental document production on July 12th. Without limitation, see RF 334-54, 358-79, 428-37, 581-755 and 1315-18. Roquette has located a few documents that marginally relate to test methodologies and protocols, which in a continued spirit of cooperation, will be produced early next week. We thus reiterate and confirm that to the extent that non-privileged information responsive to this category has been located after diligent search, it has been produced.

In light of Roquette's document production and repeated confirmation that it has no objection to providing non-privileged responsive information, we reject your contention of August 15th that Roquette refuses to either identify responsive documents or confirm that further information is not in its possession, custody or control.

Further in light of Roquette's repeated confirmation, SPI's request to personally inspect original documents is inappropriate. There is simply no basis to challenge the integrity of Roquette's discovery responses, or to suggest that Roquette is withholding relevant information. For its part, SPI has produced copies of hundreds of pages that are virtually entirely redacted. SPI's request to personally inspect that which Roquette has already

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confirmed to be non-responsive notebook entries (relating to other products or potentially patentable ideas) is unwarranted.

## II. Conception and Reduction to Practice

Roquette indicated in its July 12, 2007 letter that it had already produced information relating to conception and reduction to practice of the invention claimed in the '777 patent, and that it would supplement its interrogatory response to, *inter alia*, identify for SPI where those documents could be found. On July 27, 2007, Roquette supplemented its interrogatory response accordingly, noting that the requested information can be derived or ascertained from, e.g., RF 479-578.

Rule 33(d) provides that it can be sufficient for an interrogatory answer to specify the records from which the answer may be derived or ascertained. The documents produced provide a sequential chronology of the invention. Moreover, SPI has noticed the depositions of the two inventors and will have the opportunity to ask questions regarding these documents.

SPI's August 15th request to personally inspect the original notebooks from which Roquette produced responsive excerpts is both misplaced and again inappropriate. SPI contends that it needs to review the original notebooks to confirm that Roquette has not withheld information (despite Roquette's repeated confirmation that it has not) relating to test methodologies, protocols and raw data. However, such testing information is already addressed in item I above. Moreover, SPI's request to inspect original lab notebooks constitutes an unwarranted challenge to the veracity of Roquette's confirmation that it has not withheld responsive non-privileged information. In any event, after further review by French counsel, Roquette again confirms that the non-produced portions of the original lab notebooks contain only non-responsive information including information which is highly sensitive and confidential. Despite the protective order in place, Roquette need not reveal its business sensitive information that is unrelated to this action or SPI's information requests.

## III. Roquette's Prior Foreign Patents

We incorporate here our July 20, 2007 response to this request. Any products that may or may not be covered by patents to different inventions, published by the French Patent Office more than seven years prior to the foreign priority filing date of the patent-in-suit, have no apparent relevance to any claim or defense in this case.

SPI's argument that the French '045 and '046 patents are cited in the background discussion of the '777 patent does not establish any nexus between the claims of the '777 patent and products which may or may not be within the claims of foreign patents covering different inventions.

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#### **IV. U.S. and Foreign Prosecution Histories**

Roquette has already produced the prosecution history of the patent-in-suit. Moreover, despite its stated objection that foreign counterpart patents, much less their prosecution histories, have no bearing on any claim or defense in this case, Roquette informed SPI on July 20, 2007 that it would assemble and produce the prosecution histories for its foreign counterpart patents.

Those foreign prosecution histories are being gathered and, as indicated, will be produced once they are received.

Thus, SPI's August 15th contention that Roquette refuses to produce these documents is incorrect.

Sincerely,

  
Jeffrey R. Snay